IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

MDL No. 2545

IN RE: TESTOSTERONE REPLACEMENT
THERAPY PRODUCTS LIABILITY LITIGATION

Master Docket Case No. 1:14-cv-01748

Honorable Matthew F. Kennelly

This document applies to:

Schleck v. Auxilium Pharm. Inc., et al.,

Case No. 1:15-cv-9712

PLAINTIFF'S LOCAL RULE 56.1 RESPONSE TO DEFENDANTS' STATEMENT OF FACTS IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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Plaintiffs' Co-Lead Counsel on behalf of Plaintiffs' Steering Committee

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56.1, Plaintiff Michael Schleck submits the following statement of facts which are undisputed.

	1.	Admit.
	2.	Admit.
	3.	Admit.
	4.	Admit.
	5.	Admit.
	6.	Disputed that smoking one cigar per week is a risk factor for cardiovascular
disease	e, which	is the subject of Plaintiff's previously filed Daubert motion.
	7.	Admit.
	8.	Admit.
	9.	Admit.
	10.	Admit.
	11.	Admit.
	12.	Admit.
	13.	Admit.
	14.	Admit.
	15.	Admit.
	16.	Admit.
	17.	Admit.
	18.	Admit.
	19.	Disputed as to the characterization of Mr. Schleck's testosterone levels in his
blood s	serum a	s "low."

20.	Disputed as to the characterization of Mr. Schleck's testosterone levels in his	
blood serum as "low."		
21.	Admit.	
22.	Admit.	
23.	Admit.	
24.	Admit.	
25.	Admit.	
26.	Admit.	
27.	Admit.	
28.	Admit.	
29.	Disputed. Whether Dr. Pugh would still prescribe Mr. Schleck Testim and	
whether Dr. P	ugh would still give the same warnings he gave Mr. Schleck at the time of his	
initial prescription are disputed issues of fact.		
30.	Admit that Dr. Pugh testified that he believes his decision to prescribe medicines	
to his patients	s are based on his independent medical judgment. It is a question of fact as to	
whether that decision truly is and was independent of Auxilium's influence.		
31.	Admit.	
32.	Admit.	
33.	Admit.	
34.	Admit.	
35.	Admit.	

PLAINTIFF'S STATEMENT OF MATERIAL FACTS

- 1. Testim sales representatives called Dr. Pugh at least 116 times, which included at least 8 sales presentations that included a meal or snack. *See* Defense Fact Sheet at 1207-8; Pugh Tr. at 167:6-18.
- 2. Testim sales representatives provided copies of company-approved Testim promotional materials to Dr. Pugh. *See* DFS at 38-70; Pugh Tr. at 129:13-16.
- 3. During Mr. Schleck's course of Testim usage, Dr. Pugh believed that fatigue, weight gain, and lack of libido are the main symptoms of "hypogonadism." Pugh Tr. at 36:2-3.
- 4. During Mr. Schleck's course of Testim usage, Dr. Pugh believed that for men with these symptoms, TRT products provide a treatment option to decrease obesity and improve lipid profile, lean muscle mass, and insulin sensitivity. *Id.* at 33:5-34:14.
- 5. During the course of Mr. Schleck's usage of Testim, Dr. Pugh was unaware of the risk of myocardial infarction associated with Testim. *Id.* at 186:3-23; 193:3-11.
- 6. Dr. Pugh's risk-benefit discussion with Mr. Schleck regarding Testim was consistent with what Dr. Pugh understood the product label available at the time. *Id.* at 186:3-23; 191:15-18.
- 7. Mr. Schleck was not diagnosed with primary hypogonadism or any other condition indicated in Testim's label. *Id.* 139:14-140:15.
- 8. Dr. Pugh prescribed Testim to Mr. Schleck because of his advanced age and because he had fatigue and weight gain. *Id.* at 116:14-117:7; 140:9-15.
- 9. Prior to Mr. Schleck's myocardial infarction, Dr. Pugh never warned Mr. Schleck that Testim carried the risk of heart attack. *Id.* at 160:5-23; 193:3-11.
- 10. Dr. Pugh would not have prescribed Testim to Mr. Schleck if it did not confer a benefit. *Id.* at 141:23-142:2.

- 11. Dr. Pugh views the FDA as authoritative as to prescription drug products, and he was unaware of the FDA's view that Testim lacked efficacy for age-related hypogonadism at the time he prescribed Testim to Mr. Schleck. *Id.* at 150:18-151:6; 155:1-8; 151:3-6; 153:7-12.
- 12. Had Dr. Pugh known that Testim carried the risk of myocardial infarction, he would have not prescribed Testim to Mr. Schleck or, at a minimum, would have shared that information with Mr. Schleck during their risk-benefit discussion. *Id.* at 158:3-13.
- 13. Had Dr. Pugh known that there was insufficient evidence to establish a benefit with Testim or that Testim had potential cardiovascular risks in January 2013, he would have discussed with Mr. Schleck less risky treatment options than the use of testosterone. *Id.* at 158:21-160:4.
- 14. Mr. Schleck depended on Dr. Pugh to advise him of Testim's risks and benefits. Schleck Tr. at 164:9-12.
- 15. Mr. Schleck discontinued using Testim as soon as he was informed that Testim could cause heart attacks. *Id.* at 157:17-22.

CERTIFICATE OF SERVICE

I hereby certify that on March 2, 2018, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/ Brendan A. Smith
Brendan A. Smith